

REMARKS

Reconsideration of the present application, as amended, is respectfully requested. This application includes claims 39-60, as amended, pending and under consideration.

Reconsideration of the present application as amended in view of the remarks that follow, taken together with the attached Declaration Under 37 C.F.R. §1.132, is respectfully requested.

In the Office Action mailed June 16, 2005, claims 39-73 were pending. Claims 61-73 have been withdrawn from consideration, and claims 39-60 stand rejected.

As an initial matter, Applicant would draw the Examiner's attention to the amendments to the Markush Group (1) of claims 39, 58 and 59 to include "an organic solvent" and the amendments to the Markush Group (2) of Claims 39 and 58 to include "paraffin wax" and "microcrystalline wax." Support of the selection of an organic solvent as the fluid base material is found in the specification at page 12 lines 21-23. Support of the selection of paraffin wax as component (2) is found in the specification at page 16 lines 20-22. Support of the selection of microcrystalline wax as component (2) is found in the specification at page 16 lines 20-22.

Applicant submits that these amendments do not raise any new or unique issues, and that the amended claims are in condition for allowance for the reasons set forth herein.

Remarks Regarding Rejection of Claim 51 Under 35 U.S.C. §112

Claim 51 is rejected under 35 U.S.C. §112 on the basis that the term "comfrey" lacks antecedent basis because claim 39 was amended to delete "comfrey". In reply,

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Applicant submits that the term "comfrey" in claim 51 does not require antecedent basis and that its recitation in this claim does not make this claim indefinite under 35 U.S.C. §112, second paragraph. Rather, claim 51 is clear and definite as it is currently written. Specifically, it is proper for Applicant to further limit the subject matter of claim 39 (which does not require the presence of comfrey) in such a way that "the composition comprises a member selected from the group consisting of calendula, chamomile and comfrey." Although the composition as recited in claim 39 does not identify comfrey as an optional ingredient, the subject recited in claim 39 must be given an open interpretation whereby additional ingredients can be included. Thus, a composition that reads on claim 39 CAN include comfrey, and to further specify in claim 51 that one of calendula, chamomile and comfrey is present in the composition is simply to further limit the subject matter of claim 39. Applicant therefore submits that this rejection is improper and withdrawal thereof is respectfully requested.

Remarks Regarding Rejections of Claims Under 35 U.S.C. §103(a)

In the outstanding Action, the Examiner has re-asserted the same rejections of the various pending claims over the same combinations of references as asserted in the prior Office Action dated November 26, 2004 (with the exception that claim 39 is no longer rejected over the combination of Adams or Gebhart et al. in view of Huffstutler). In so doing, the Examiner asserts that Applicant's arguments filed in response to the first Action have been fully considered but they are not persuasive.

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Applicant again submits, for the reasons stated herein that the pending claims are allowable over the cited references. In support of the remarks set forth herein, Applicant submits herewith a Declaration Under 37 C.F.R. §1.132 (hereafter "Declaration") to provide evidence in the record bearing on the patentability of the pending claims. In view of the remarks herein and the enclosed Declaration, Applicant respectfully submits that the pending claims are in condition for allowance, and respectfully requests withdrawal of the rejections asserted in the outstanding Action. Each combination cited by the Examiner is addressed separately below.

Remarks Regarding the Asserted Adams/Clark Combination

In the outstanding Office Action, claims 39, 40, 44-48 and 54-58 are rejected under 35 U.S.C. §103(a), as being unpatentable over Adams et al. (EP 191 128) in view of Clark et al. (US 6,103,245). In traversal of this rejection, Applicant submits that the claimed invention is not obvious over this combination of references because (1) a person of ordinary skill in the art would not have been motivated to modify the teachings of the cited references in a manner that would be necessary to arrive at the presently claimed invention, (2) the present invention proceeds contrary to accepted wisdom that existed at the time the application was filed, (3) even if a suggestion would have been made to a person of ordinary skill in the art at the time of the invention to modify a low viscosity sprayable drug-delivery composition by adding high viscosity barrier-type ingredients in amounts necessary to provide a composition having the physical properties described and claimed in the present application, he or she would have expected the operability (i.e., sprayability) of

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the spray system to be degraded to a point where the modification would not be desirable, and he or she therefore would have had no reasonable expectation of success, and (4) even if a suggestion would have been made to a person of ordinary skill in the art at the time of the application to modify a highly viscous, hydrophobic barrier composition by adding viscosity-reducing or hydrophobicity-reducing ingredients at a level necessary to provide a composition suitable for passage through an atomizing spray dispenser, as described and claimed in the present application, he or she would have expected the operability (i.e., barrier functionality) of the barrier composition to be degraded to a point where the modification would not be desirable, and he or she therefore would have had no reasonable expectation of success.

When considering the question of whether a person of ordinary skill in the art would have been motivated to combine or modify the teachings of these references in the manner suggested in the Office Action, it is important to remain focused on the physical properties of the composition that are recited in the pending claims, i.e., to note that the pending claims recite a composition having “a viscosity sufficiently low to allow the composition to be atomized upon passage through the atomizing spray dispenser and sufficiently high that the coating does not run off of the skin treatment area.” (emphasis added). Although there is a statement in the first Office Action (mailed November 16, 2004) that the Adams et al. reference “teaches compositions in the form of aerosols,” (11/16/2004 Action at Page 4), there is no acknowledgement of the importance of the claimed physical properties of the composition recited in the pending claims to the analysis,

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and there appears to have been no consideration of what would motivate a person of ordinary skill in the art in the selection of ingredients. Rather, the focus of the remarks in the Actions is solely upon the question of whether a person of ordinary skill in the art would include the identified ingredients in a diaper rash treatment composition, without regard to the physical properties of the composition, and without regard to the important fact that a person of ordinary skill in the art would have found no motivation in the prior art to deliver a barrier-type diaper rash composition via an atomizing spray dispenser in the first place. In other words, the analysis set forth in the Office Actions overlooks the importance of the fact that the pending claims recite compositions having specific physical properties, namely, “a viscosity sufficiently low to allow the composition to be atomized upon passage through the atomizing spray dispenser and sufficiently high that the coating does not run off of the skin treatment area.” (emphasis added). While the Action dated 11/16/2004 suggests that the physical properties can simply be optimized to “to obtain the desired sprayability of the composition,” (11/16/2004 Action, Page 5), this conclusory statement ignores the fact that a person of ordinary skill in the art would not have attempted to optimize physical properties in this manner because he or she would have had no expectation that a barrier-type diaper rash composition could even be formulated to have acceptable sprayability characteristics and also acceptable barrier functionality when spray coated on a skin treatment area. (Declaration, Paragraph 5).

The outstanding Action asserts that a person of ordinary skill in the art would be motivated to combine these references because Adams et al. pertains to “the difficulties in

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'protecting the baby's bottom from prolonged exposure to the effects of ammonium compounds on the baby's skin' and caring for skin irritations such as chapping, rashes, reddening, tenderness and the like," and Clark et al. indicate "success in using micronized zinc oxide, silicone and/or petrolatum in topical barrier compositions." (06/16/2005 Action at Page 4). These statements ignore that the references lack any suggestion to attempt to formulate a barrier-type diaper rash composition that could be delivered via an atomizing spray dispenser. The Action asserts that a person of ordinary skill in the art would be motivated to combine the references simply because both references describe compositions that can be used to treat diaper rash, and thus ingredients that can be used to treat diaper rash. However, simply combining ingredients that are considered to be acceptable for inclusion in a diaper rash treatment composition is not sufficient to arrive at the present invention as recited in the pending claims, and the identification of all known ingredients that might be suitable for inclusion in a diaper rash composition would not have motivated or enabled a person of ordinary skill in the art to practice the present invention.

(Declaration, Paragraph 6). Indeed, a person of ordinary skill in the art at the time of the present application would not have believed that a composition could even be formulated to be capable of BOTH being applied to a skin treatment area via an atomizing spray dispenser AND providing a suitable barrier functionality for the treatment of diaper rash.

(Declaration, Paragraph 6). These characteristics are at odds with one another, and a person of ordinary skill in the art would not have believed that such a formulation could be developed. (Declaration, Paragraph 6). There is certainly no description or suggestion in

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the cited references of a composition that has both of these capabilities. Absent the motivation provided by the present invention, a person of ordinary skill in the art would not have combined ingredients from the respective references in a manner that would be necessary to practice the present invention. (Declaration, Paragraph 6).

Given that simply selecting ingredients from the various references itself is not sufficient to arrive at the present invention, a person of ordinary skill in the art would need to find further motivation to combine suitable ingredients in a suitable manner to provide a composition that has physical properties that "allow the composition to be atomized upon passage through the atomizing spray dispenser" and with a viscosity "sufficiently high that the coating does not run off of the skin treatment area." Neither of the cited references supplies the motivation to combine ingredients in this manner, as the present application describes and claims. (Declaration, Paragraph 7). There is simply no teaching or suggestion of a composition in the cited references that has the combination of physical properties discussed herein.

It is also noteworthy that the disclosure of Adams et al., within its four corners, provides support for the contentions of the preceding paragraphs. In particular, Adams et al. describes a variety of delivery systems featuring a variety of different physical forms for delivering 8 Hydroxy Quinoline Sulfate or Parachlorometaxylenon to treat a skin irritation, and all of the compositions described therein include barrier-type ingredients EXCEPT the sprayable compositions described therein. The various physical forms of carrier formulations for delivering the active agent 8 Hydroxy Quinoline Sulfate or the active

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agent Parachlorometaxylenol described in Adams et al. include wipe-on stick form, lotion form, powder form, aerosol form, cream form, ointment form, jelly form and oil form. It is important to recognize, however, that although some of the formulations described in Adams et al. do include some barrier-type ingredients, there is no mention of any of these barrier-type ingredients being included in any of the sprayable compositions described in Adams et al., even though sprayable drug delivery systems are described therein. Indeed, all of the formulations described in Adams et al. as being sprayable are very low viscosity compositions that would be incapable of forming a coating on a skin treatment area without running off of the skin treatment area. (Declaration, Paragraph 8). Thus, even within the four corners of the Adams et al. reference is evidence that a person of ordinary skill in the art would simply not be motivated to provide a sprayable composition that includes ingredients imparting the physical properties described and claimed in the present application. (Declaration, Paragraph 8). Thus, the Adams et al. reference and the Clark et al. reference teach away from the present invention.

The Examiner cites *In re Gurley* in support of the proposition that, "a prior art reference may be considered to teach away when 'a person of ordinary skill, upon reading the reference, ... would be led in a direction divergent from the path that was taken by the Applicant.'" (06/16/2005 Action, Page 5). A person of ordinary skill, upon reading the Adams et al. and Clark et al. references, would be led in a direction away from including viscosity-increasing barrier-type ingredients in a composition that is to be sprayed through an atomizing spray dispenser, in amounts that would be necessary to provide the physical

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properties described and claimed in the present application (i.e. physical properties that “allow the composition to be atomized upon passage through the atomizing spray dispenser” and with a viscosity “sufficiently high that the coating does not run off of the skin treatment area”). (Declaration, Paragraph 9). To make the conclusory statement in the Action that, “There is nothing in Adams et al. that ‘would discourage’ a person of ordinary skill from using ingredients of Clark et al. and formulating them into an aerosol composition,” ignores the reality of what a person of ordinary skill would have taken these references, and the entire body of prior art, to suggest. (Declaration, Paragraph 9). A person of ordinary skill in the art at the time the application was filed would have taken the references to suggest that only very low viscosity compositions are suitable for inclusion in a composition that is intended to be applied by spray delivery, and there is no indication in either of these references that a composition even exists that has the physical properties described and claimed in the present application (i.e. physical properties that “allow the composition to be atomized upon passage through the atomizing spray dispenser” and with a viscosity “sufficiently high that the coating does not run off of the skin treatment area”). (Declaration, Paragraph 9).

In addition to the above, the present invention proceeds contrary to the accepted wisdom that existed at the time the application was filed. As stated in MPEP §2145, “The totality of the prior art must be considered, and proceeding contrary to accepted wisdom in the art is evidence of nonobviousness. In re Hedges, 783 F.2d 1038, 228 USPQ 685 (Fed.Cir. 1986).” To accurately understand the suggestive effect of the cited references, and to fully appreciate what the cited references would suggest to one skilled in the art at the time of the

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invention, it is important to consider the art as a whole at the time the invention was made, including trends and beliefs in the field of diaper rash treatment and the perspective of a person skilled in the art. A person of ordinary skill in the art at the time of the present invention would have understood that all diaper rash treatment products fall into one or both of the following two categories: "protective barrier" compositions and "active agent delivery" compositions. (Declaration, Paragraph 10). Of course, a given product could belong in both categories, i.e., a protective barrier composition could also include one or more active agents. However, one important distinction between these two categories of diaper rash treatment products is the following: while active agent delivery compositions could take a wide variety of physical forms (i.e., aqueous liquids, emulsions, creams, ointments, pastes, powders or other solids), the physical form of protective barrier compositions was and is relatively uniform: a highly viscous, typically hydrophobic, paste, ointment or cream. (Declaration, Paragraph 10). Such highly viscous compositions were believed to be necessary to provide a suitable protective barrier product. (Declaration, Paragraph 10).

Significant efforts have been made in the prior art, and significant resources have been devoted to efforts to identify the precise cause or causes of diaper rash, with the belief that this would enable the development of formulations that include active ingredients selected to address the cause more directly. (Declaration, Paragraph 11). Even in view of significant efforts to identify the specific cause of diaper rash, it was generally believed at the time the present application was filed, and is generally believed at this time, that the most important feature of a diaper rash treatment composition is its ability to provide a

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physical, non-soluble barrier between urine and/or feces and the underlying skin.

(Declaration, Paragraph 11). As stated at page 3 of the present application:

Because the suspected agents of diaper rash ... all possess diverse properties and require varied therapies, conventional methods of treatment for diaper dermatitis have been directed toward a straightforward attempt to minimize the contact of the skin with the feces or urine present in a soiled diaper. An artificial barrier is usually provided between the skin and the body waste to accomplish this... [Because] the exact components of urine or feces which act as factors or cofactors contributing to diaper dermatitis have never been precisely identified, the most effective method of treating diaper rash to date has been the artificial barrier.

In keeping with the trend of providing an artificial barrier in conventional treatments of diaper rash, a wide variety of highly viscous pastes, ointments and creams have been developed to be applied to skin in an effort to provide a suitable barrier to prevent skin contact with urine and/or fecal matter. (Declaration, Paragraph 12). Because urine is an aqueous liquid, and fecal matter sometimes also has a high water content, it has been long understood and widely accepted that, to be effective, the paste, ointment or cream should be formulated as a highly viscous, hydrophobic preparation. (Declaration, Paragraph 12).

In view of this background, it is apparent that the present invention proceeds contrary to the accepted wisdom that existed at the time the application was filed. A person of ordinary skill in the art at the time of the present invention would have understood the limitations on the physical characteristics of ingredients in a barrier composition, and would not have been motivated to add ingredients into a barrier formulation that would reduce the viscosity or hydrophobicity thereof, much less try to formulate a barrier composition that could be passed through an atomizing spray delivery mechanism.

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(Declaration, Paragraph 13). Similarly, a person of ordinary skill in the art would have had no motivation to pluck ingredients from a "protective barrier" composition for inclusion in a liquid "active agent delivery" composition. (Declaration, Paragraph 13).

Even in the event a suggestion would have been made explicitly to a person of ordinary skill in the art at the time of the application to modify a low viscosity sprayable composition by adding high viscosity barrier-type ingredients at a level necessary to provide a composition having the physical properties described and claimed in the present application, he or she would have expected the operability (i.e., sprayability) of the spray system to be degraded to a point where the modification would not be desirable.

(Declaration, Paragraph 14). He or she therefore would have had no reasonable expectation of success, and would not have been motivated to even attempt to make such modifications. (Declaration, Paragraph 14). Similarly, but from a different perspective, in the event a suggestion would have been made explicitly to a person of ordinary skill in the art at the time of the application to modify a highly viscous, hydrophobic barrier composition by adding viscosity-reducing or hydrophobicity-reducing ingredients in amounts necessary to make a composition suitable for passage through an atomizing spray dispenser, as described and claimed in the present application, he or she would have expected the operability (i.e., barrier functionality) of the barrier system to be degraded to a point where the modification would not be desirable, and he or she therefore would have had no reasonable expectation of success, and would not have been motivated to even attempt to make such modifications. (Declaration, Paragraph 14). It is believed that the

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prior art is devoid of any information suggesting that the combination of properties recited in the pending claims would be achievable in a composition as recited in the pending claims, as amended. A person of ordinary skill in the art at the time of this application would not have expected any composition having a viscosity "sufficiently high that the coating does not run off of the skin treatment area" as recited in the claims, as amended, also to be suitable for delivery through an atomizing spray dispenser, as also recited in the pending claims, as amended. (Declaration, Paragraph 14).

In view of the above, Applicant submits that neither Adams et al. nor Clark et al., nor any other reference of record in this case, would be understood by a person of ordinary skill in the art to provide any teaching, suggestion or motivation to modify their teachings in a manner that would lead to the present invention. (Declaration, Paragraph 18). While each of Adams et al. and Clark et al. describes a composition that can be used as a treatment for diaper rash, the assertions in the outstanding Action ignore that a person of ordinary skill in the art at the time of the invention would not have combined the references to arrive at the present invention, as suggested in the outstanding Action. (Declaration, Paragraph 18). A person of ordinary skill in the art would find no motivation in these references to use a highly viscous paste, ointment or cream, or the ingredients thereof, in an aerosol system, or any other type of spray system. (Declaration, Paragraph 18). A person of ordinary skill in the art would not have modified a highly viscous paste, ointment or cream protective barrier formulation to make it sprayable, and would not have selected ingredients thereof for inclusion in a spray-on diaper rash composition. (Declaration, Paragraph 18). Similarly,

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but from another perspective, a person of ordinary skill in the art would not have modified a low viscosity sprayable composition by adding high viscosity barrier-type ingredients at a level necessary to provide a barrier-type composition, and would not have selected ingredients thereof for inclusion in a barrier-type ointment. (Declaration, Paragraph 18).

Applicant therefore submits that the rejection of claims 39, 40, 44-48 and 54-58 under 35 U.S.C. §103(a), as being unpatentable over Adams et al. (EP 191 128) in view of Clark et al. (US 6,103,245) is overcome, and respectfully requests withdrawal of same.

Remarks Regarding the Asserted Gebhart/Moss Combination

In the outstanding Office Action, claims 39, 40, 44 and 54-58 are rejected under 35 U.S.C. §103(a), as being unpatentable over Gebhardt et al. (US 3,584,115) in view of Moss (US 4,816,254). In traversal of this rejection, Applicant submits that the claimed invention is not obvious over this combination of references because there is no teaching, suggestion or motivation to be found in the cited references or in the prior art as a whole to modify the cited references in a manner that would be necessary to arrive at the present invention.

Gebhardt et al., like Adams et al. discussed above, describes "aerosol compositions for the treatment of skin irritations such as diaper rash." The formulations described by Gebhart et al., like those described by Adams et al., do not provide moisture barrier protection. The Examiner states that, "Gebhart et al. do not teach the component (2) of the instant claims," but states that various missing ingredients are supplied by Moss. In reply, Applicant submits that many of the same principles set forth above concerning the asserted Adams/Clark combination apply equally well to the Gebhardt/Moss combination and other

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combinations asserted in the outstanding Action. With respect to the rejection of claims 39, 40, 44 and 54-58 over the Gebhardt/Moss combination, Applicant submits that the invention recited in these claims is not obvious over this combination because (1) a person of ordinary skill in the art would not have been motivated to modify the teachings of the cited references in a manner that would be necessary to arrive at the presently claimed invention, (Declaration, Paragraph 19), (2) the present invention proceeds contrary to accepted wisdom that existed at the time the application was filed, (Declaration, Paragraph 19), and (3) even if a suggestion would have been made explicitly to a person of ordinary skill in the art at the time of the invention to modify a sprayable composition by adding barrier-type ingredients at a level necessary to provide a composition having the physical properties described and claimed in the present application, he or she would have expected the operability (i.e., sprayability) of the spray system to be degraded to a point where the modification would not be desirable, and he or she therefore would have had no reasonable expectation of success. (Declaration, Paragraph 19). Likewise, in the event a suggestion would have been made explicitly to a person of ordinary skill in the art at the time of the application to modify a highly viscous, hydrophobic barrier composition by adding viscosity-reducing or hydrophobicity-reducing ingredients at a level necessary to provide a composition suitable for passage through an atomizing spray dispenser, as described and claimed in the present application, he or she would have expected the operability (i.e., barrier functionality) of the barrier system to be degraded to a point where the modification would not be desirable, and he or she therefore would have had no reasonable expectation

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of success, and would have derived no motivation from the cited references to make these modifications. (Declaration, Paragraph 19).

Applicant submits that there is no motivation to combine the Gebhart et al. and Moss references in the manner suggested in the Action for the same reasons that there is no motivation to combine the Adams et al. and Clark et al. references, discussed above. The undersigned therefore submits that the cited references do not teach or suggest a method as recited in the subject claims, and would not motivate a person of ordinary skill in the art to modify the references to arrive at the present invention. Withdrawal of this rejection is also respectfully requested.

Remarks Regarding the Asserted Adams/Clark/Boussouire Combination

In the outstanding Office Action, claims 41-43, 59 and 60 are rejected under 35 U.S.C. §103(a), as being unpatentable over Adams et al. (EP 191 128) in view of Clark et al. (US 6,103,245) and further in view of Boussouira et al. (US 6,103,247). In traversal of this rejection, Applicant submits that the Adams et al. and Clark et al. references are not properly combined for the same reasons as set forth above, and that the Boussouira et al. reference also fails to provide any motivation to combine the references. As such, Applicant submits that this rejection is also improper for at least the same reasons that the rejection of claims over a combination of Adams et al. and Clark et al. is improper.

Remarks Regarding the Asserted Adams/Gebhart/Mulder/Moss Combination

In the outstanding Office Action, claims 39, 49 and 50 are rejected under 35 U.S.C. §103(a), as being unpatentable over either Adams et al. (EP 191 128) or Gebhart et al. (US

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3,584,115) in view of Mulder (US 5,536,502) and Moss (US 4,816,254). In traversal of this rejection, Applicant submits that neither the Adams et al. reference nor the Gebhart et al. reference is properly combined with the Moss references for the same reasons as set forth above with respect to the Adams/Clark and Gebhart/Moss combinations, and that the Mulder reference also does not support this rejection.

Reference is made in the Action to the Mulder patent in support of the proposition that a person of ordinary skill in the art would be motivated to include viscosity-increasing ingredients in a diaper rash spray composition. In this regard, the Action states that, "This is further supported by the teachings of Mulder, who teaches using zinc oxide as well as lanolin oil, waxes, fatty acids, fatty esters and other high viscosity ingredients in spray-on wound healing formulations." (06/16/2005 Action at Pages 5-6).

Applicant submits that Mulder is nonanalogous art. As stated in MPEP §2141.01(a), "In order to rely on a reference as a basis for rejection of an applicant's invention, the reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned." Mulder cannot be relied upon as a basis for rejection of claims in the present application because it does not satisfy either of these two requirements.

Mulder is not in the field of applicant's endeavor. As stated at page 1 of the present application, "The present invention relates to methods, compositions and systems for the prevention and treatment of diaper rash." In contrast, Mulder states at Column 1, lines 7-9 that, "The present invention pertains to the field of topical ointments and, more particularly,

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to products that are used for the treatment of superficial lesions including skin tears.” It is stated in the Office Action that Mulder is in the same field of endeavor as the present invention “because both inventions are concerned with skin healing.” Applicant respectfully disagrees with this statement. It is important to recognize that the field of endeavor involving treating skin tear wounds is significantly different than the field of endeavor involving treatment and prevention of diaper rash. (Declaration, Paragraph 16). A person of ordinary skill in the field of skin tear wounds would understand the importance of giving careful attention to cleaning any and all debris and infectious agents from the wound, applying medicines to the wound, keeping the wound clean, and ensuring that an unrestricted amount of oxygen is able to reach the wound to allow proper healing. (Declaration, Paragraph 16). With respect to the latter, a person of ordinary skill in the field of skin tear treatment would readily understand that a barrier-type composition such as those discussed in the present application, should never be applied over a skin tear wound. (Declaration, Paragraph 16). Numerous studies have shown that the proper healing of skin-breaking wounds is prevented by moisture barrier-type, or “occlusive” products, suppress recovery and reduce the epidermal proliferative response to the wound, while semipermeable, or “breathable,” materials do not slow recovery and allow for normal cellular respiration. (Declaration, Paragraph 16). Thus, a barrier-type composition, or “occlusive product,” as described and claimed in the present application simply should not be used in the field of wound care. (Declaration, Paragraph 16). In contrast, the field of diaper rash treatment, as discussed in detail herein, involves the placement of a robust and

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impermeable (non-breathable) barrier over an area of skin having, or at risk of experiencing, diaper rash. A barrier composition of this type would be totally unsuitable for placement on an open wound. Thus, barrier-type diaper rash treatment compositions should never be considered desirable for use in connection with a skin tear, and the two are properly considered different fields of endeavor. (Declaration, Paragraph 16).

Mulder is also not reasonably pertinent to the particular problem with which the inventor was concerned. In the development of the present invention, the particular problem with which the inventor was concerned was that:

products currently available for the treatment of diaper rash...are very viscous and messy to administer to the skin. Such products require that the person applying the product spread the product by rubbing the same into or over the skin. While this requirement is typically acceptable in the case of a parent applying the product to the skin of an infant child, it is a drawback where a caregiver is in charge of providing such a treatment to multiple persons, especially multiple incontinent adults. The application of the product is messy and awkward because the product is difficult to wash off of ones hand due to its oily, hydrophobic nature. Additionally, the caregiver must first use one set of gloves to clean the patient, and then use another set of gloves to apply the ointment or lotion. This results in wasted time and resources.

(Specification, Page 5, lines 3-13). Mulder is not reasonably pertinent to this problem relating to the mess and inefficiency of applying an oily, hydrophobic ointment to a skin treatment area. (Declaration, Paragraph 17). Rather, Mulder is focused upon addressing the "need for a non-irritating, topical ointment or medicament that is specifically designed to promote the reepithelialization of skin tears." (Mulder, Column 2, lines 18-20). This is not reasonably pertinent to the problem with which the present inventor was concerned

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because a product capable of promoting the reepithelialization of skin tears would not be pertinent to the problem of the mess and inefficiency of applying an oily, hydrophobic diaper rash ointment to a skin treatment area. (Declaration, Paragraph 17). Furthermore, an oily, hydrophobic barrier-type diaper rash composition should never be used for treating skin tears, because a barrier composition would cause a significant impediment to wound healing. (Declaration, Paragraph 17). Indeed, the compositions described by Mulder are designed around the concept of washing/flushing the wound site, and thus only a small proportion of the composition applied to the wound would even remain after the flushing was completed. (Declaration, Paragraph 17). This is a fundamentally different purpose than the purpose of a barrier-type diaper rash composition, which functions optimally by being retained on the skin in its entirety. (Declaration, Paragraph 17). Thus, the properties that would be desirable in the respective types of compositions are significantly different. (Declaration, Paragraph 17). As such, Mulder is nonanalogous art because it is not in the field of applicant's endeavor or reasonably pertinent to the particular problem with which the inventor was concerned.

Applicant therefore respectfully submits that the rejection of claims 39, 49 and 50 as being unpatentable over either Adams et al. or Gebhart et al. in view of Mulder and Moss is overcome, and respectfully requests withdrawal of same.

Remarks Regarding the Asserted Adams/Gebhart/Huffstutler Combination

In the outstanding Office Action, claims 51 and 52 are rejected under 35 U.S.C. §103(a), as being unpatentable over either Adams et al. (EP 191 128) or Gebhart et al. (US

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3,584,115) in view of Huffstutler (WO 92/06701). The Huffstutler reference is cited in the Action as teaching "using comfrey extract in topical compositions for its healing properties and ability to stimulate epithelial development in the case of skin damage or breakdown." In traversal of this rejection, Applicant submits that neither the Adams et al. reference nor the Gebhart et al. reference is not properly combined with Huffstutler for the same reasons as set forth above with respect to the Adams/Clark and Gebhart/Moss combinations. Applicant therefore respectfully submits that this combination of references likewise does not support the asserted rejection of claims 51 and 52.

Remarks Regarding the Asserted Adams/Gebhart/Huffstutler/Moss Combination

In the outstanding Office Action, claim 53 is rejected under 35 U.S.C. §103(a), as being unpatentable over Adams et al. (EP 191 128) or Gebhart et al. (US 3,584,115) in view of Huffstutler (WO 92/06701) and further in view of Moss (US 4,816,254). Because the combination of Adams et al. or Gebhart et al. with Huffstutler fails to support a *prima facie* case of obviousness for the reasons set forth above, and Moss fails to overcome the failings thereof, Applicant respectfully submits that this combination of references likewise does not support the asserted rejection of claim 53.

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Closing

Applicant submits that, when properly considered, the only suggestion of the presently claimed invention is provided by the present application. One having ordinary skill in the art at the time of the invention would not have derived any motivation from the cited references to make modifications to the described compositions that would have been necessary to arrive at the invention as recited in the present claims, as amended. Applicant therefore respectfully submits that claims 39-60, as amended, are allowable over the cited references and request that the rejection of these claims under 35 U.S.C. § 103(a) be withdrawn.

In view of the above, Applicant respectfully submits that the rejections stated in the outstanding Action are overcome and that the present application, as amended and including claims 39-60, is in condition for allowance. Action to that end is respectfully requested. If there are any remaining issues that can be addressed telephonically, the Examiner is invited to contact the undersigned to discuss the same.

Respectfully submitted,

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